FOR FURTHER INFORMATION CONTACT: Sandra M. Peay, Contact Representative, Premerger Notification Office, Bureau of Competition, Room 301, Federal Trade Commission, Washington, DC 20580, (202) 326-3100.

By director of the Commission.

Emily H. Rock,

Secretary.

[FR Doc. 88-6890 Filed 3-29-88; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Suspension of Eligibility for Financial Assistance; Dr. Claudio Milanese

AGENCY: Department of Health and Human Services (HHS).

ACTION: Notice of Suspension.

SUMMARY: This notice announces the suspension of Dr. Claudio Milanese from eligibility for direct or indirect financial assistance under any discretionary program awarded or administered by the Department of Health and Human Services.

DATES: The suspension became effective February 19, 1988 and is for a temporary period pending the completion of debarment proceedings.

FOR FURTHER INFORMATION CONTACT: Robert B. Lanman, Esq., Chief, National Institutes of Health Branch, Public Health Division, Office of General Counsel, 9000 Rockville Pike, Building 31, Room 2B-50, Bethesda, Maryland 20892. Telephone: (301) 496-4108.

SUPPLEMENTARY INFORMATION: Pursuant to 45 CFR Part 76, Dr. Claudio Milanese, Corso G. Marconi 24, 10125 Torino, Italy, has been suspended from receiving or applying for, directly or indirectly, any form of financial assistance under any discretionary program awarded or administered by the Department of Health and Human Services. It also suspends Dr. Milanese from service or participation in the conduct or performance of an assisted project. The suspension became effective on February 19, 1988 and is for a temporary period pending the completion of debarment proceedings. This action is being taken pursuant to the HHS Financial Assistance Debarment and Suspension Regulations pertaining to grants and other forms of financial assistance, 45 Code of Federal Regulations, Part 76.

The basis for the suspension action is that there is reasonable evidence Dr. Milanese has committed irregularities of a serious nature which are grounds for debarment under 45 CFR 76.10. The investigative report concluded that Dr. Milanese was responsible for three types of fabrication: (1) Frank invention of data; (2) supplying of fraudulent research materials to collaborators; and (3) tidying of data to improve the published results. The instances of serious deviation from accepted medical research practices set forth in the investigative report reflect his failure to comply with the fundamental duty of research scientists to report accurately the methods and results of their research and otherwise reflect a lack of integrity, care and judment that is so compelling as to seriously and directly affect his participation in HHS financial assistance.

Dated: March 23, 1988.

Henry G. Kirschenmann, Jr.,

Deputy Assistant Secretary for Procurement, Assistance and Logistics.

[FR Doc. 88-6909 Filed 3-29-88; 8:45 am]

BILLING CODE 4150-04-M

Alcohol, Drug Abuse, and Mental Health Administration

Establishment of Extramural Science Advisory Board

Pursuant to the Federal Advisory Committee Act of October 6, 1972, (Pub. L. 92-463, 86 Stat. 770-776) the Secretary, Health and Human Services, announces the establishment of the Extramural Science Advisory Board, NIAAA, on March 8, 1988.

March 25, 1988.

Donald Ian Macdonald,

Administrator, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 88-6931 Filed 3-29-88; 8:45 am]

BILLING CODE 8230-01-M

Food and Drug Administration

[Docket No. 88E-0067]

Determination of Regulatory Review Period for Purposes of Patent Extension; Novantrone™

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Novantrone™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

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ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: I. David Wolfson, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) generally provides that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under that act, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Novantrone™ (mitoxantrone hydrochloride), which is an antineoplastic agent used in the initial therapy of acute nonlymphocytic leukemia. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Novantrone™ (U.S. Patent No. 4,278,689) from the American Cyanamid Co. and requested FDA's assistance in determining the patent's eligibility for patent term restoration. FDA, in a letter dated March 7, 1988, advised the Patent and Trademark

Office that the human drug product had undergone a regulatory review period and that the active ingredient, mitoxantrone hydrochloride, represented the first commercial marketing or use of that active ingredient. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Novantrone™ is 3,145 days. Of this time, 1,836 days occurred during the testing phase of the regulatory review period, while 1,309 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* May 16, 1979. The applicant claims April 16, 1979, as the date the investigational new drug application (IND) for the drug became effective. However, FDA records indicate that the IND was received on April 16, 1979 and pursuant to FDA regulations, became effective on May 16, 1979.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* May 24, 1984. The applicant claims that a new drug application for Novantrone™ (NDA 19–297) was initially submitted on May 18, 1984. However, FDA did not receive the application until May 24, 1984.

3. *The date the application was approved:* December 23, 1987. FDA has verified the applicant's claim that NDA 19–297 was approved on December 23, 1987.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 31, 1988, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before September 26, 1988, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 23, 1988.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 88–6885 Filed 3–29–88; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 88M–0082]

Wesley-Jessen; Premarket Approval of Durasoft® 4 (Ofilcon A) Hydrophilic Contact Lens

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of a supplemental application by Wesley-Jessen, Chicago, IL, for premarket approval, under the Medical Device Amendments of 1976, of the spherical DURASOFT® 4 [ofilcon A] HYDROPHILIC CONTACT LENS (clear and tinted). After reviewing the recommendation of the Ophthalmic Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant of the approval of the supplemental application.

DATE: Petitions for administrative review by April 29, 1988.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA 305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David M. Whipple, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7940.

SUPPLEMENTARY INFORMATION: On November 12, 1987, Wesley-Jessen, Chicago, IL 60610, submitted to CDRH a supplemental application for premarket approval of the DURASOFT® 4 (ofilcon A) HYDROPHILIC CONTACT LENS (clear and tinted) for an aphakic indication. The lens is indicated for daily wear and extended wear from 1 to 30 days between removals for cleaning and disinfection as recommended by the eye care practitioner. The lens is indicated for the correction of visual acuity in aphakic and not-aphakic persons with nondiseased eyes that are myopic or hyperopic. The tinted lens provides for ease of patient handling and does not affect iris color. The lens may be worn by persons who may exhibit astigmatism of 2.00 diopters (D) or less that does not interfere with visual acuity. The lens ranges in powers from −20.00 D to +20.00 D and is to be disinfected using either a chemical or heat lens care system. The tinted lens contains the color additive [phthalocyaninato(2-)] copper in accordance with the color additive listing provisions of 21 CFR 74.3045.

On January 22, 1988, the Ophthalmic Devices Panel, an FDA advisory committee, reviewed and recommended approval of the supplemental application. On February 24, 1988, CDRH approved the supplemental application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact David M. Whipple (HFZ–460), address above.

The labeling of the approved contact lens states that the lens is to be used only with certain solutions for disinfection and other purposes. The restrictive labeling informs new users that they must avoid using certain products, such as solutions intended for use with hard contact lenses only. The restrictive labeling needs to be updated periodically, however, to refer to new lens solutions that CDRH approves for use with approved contact lenses made of polymers other than polymethylmethacrylate, to comply with the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 et seq.), and regulations thereunder, and with the Federal Trade Commission Act (15 U.S.C. 41–58), as amended. Accordingly, whenever CDRH publishes a notice in the **Federal Register** of approval of a new solution for use with an approved